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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,073	09/08/2005	Venugopal K Nair	AM 101125	7581
25291	7590	10/02/2007		
WYETH PATENT LAW GROUP 5 GIRALDA FARMS MADISON, NJ 07940			EXAMINER HURT, SHARON L	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 10/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/530,073

Applicant(s)

NAIR ET AL.

Examiner

Sharon Hurt

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☒ Claim(s) 7-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>Nov. 19, 2004</u> .   | 6) <input type="checkbox"/> Other: ____                           |

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## **DETAILED ACTION**

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The certified copies filed on April 1, 2005 have been acknowledged and entered.

### ***Election/Restrictions***

During a telephone conversation with Frank Cottingham on Monday, September 24, 2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Status of the Claims***

Claims 1-21 are pending. Claims 17-21 are withdrawn from consideration. Claims 1-16 are under examination.

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***Claim Objections***

**Claims 7-16 are objected to** under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim *cannot depend from any other multiple dependent claim*. See MPEP § 608.01(n). Accordingly, the **claims 7-15 have not been further treated on the merits**.

**Claims 9 and 10 are objected to** because of the following informalities: The claims disclose primer sequences that are not labeled with sequence identifiers. Appropriate correction is required.

**Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Specifically the application fails to comply with CFR 1.821(d), which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

For compliance with sequence rules, it is necessary to include the sequence in the "Sequence Listing" and identify them with SEQ ID NO. In general, any sequence that is disclosed and/or claimed as a sequence, i.e., as a string of particular bases or amino acids, and that otherwise meets the criteria of 37 CFR 1.821(a), must be set forth in the "Sequence Listing." (see MPEP 2422.03).

For the response to this office action to be complete, Applicants are required to comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3 are rejected under 35 U.S.C. 102(b)** as being anticipated by **Davidson et al.** (Avian Pathology, June 1, 2002, Vol. 31, No. 3, pages 237-240).

The claimed invention is drawn to a method of detecting a virus in an avian tissue sample comprising: extracting genetic material from an avian tissue sample; and testing for a virus; the avian tissue sample is from feathers, wherein the method provides quantitative information, wherein the virus is MDV.

Davidson et al. (hereinafter Davidson) teaches about testing feather-tip DNA for Marek's disease virus (MDV) and avian leucosis virus, subgroup J (ALV-J) (Abstract). Davidson also teaches DNA was extracted from feather tips for MDV diagnosis by PCR (page 238, Results and Discussion).

**Claims 1-5 are rejected under 35 U.S.C. 102(b)** as being anticipated by **Handberg et al.** (Avian Pathology, June 1, 2001, Vol. 30, No. 3, pages 243-249).

The claimed invention is drawn to the claimed invention described above wherein the method is specific for MDV serotype 1 or MDV-1 Rispens strain CVI 988.

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Handberg et al. (hereinafter Handberg) teaches a method for detecting Marek's disease virus (MDV) by polymerase chain reaction (PCR) using various tissue samples from chickens, including feather tips conveniently collected in the field (Abstract). Handberg teaches the method is sensitive and specific for MDV serotype 1 including strain CVI988 (Abstract). PCR was performed on the purified DNA samples using two primer sets, oligonucleotides specific for MDV serotype 1 (page 245, Polymerase Chain Reaction). Handberg teaches all the limitations of the instant claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-6 are rejected under 35 U.S.C. 103(a)** as being unpatentable over **Handberg** et al. in view of **Becker** et al. (Virus Genes, 1993, Vol. 7, No. 3, pages 277-287).

The claimed invention is drawn to the claimed invention described above wherein the method comprises providing a forward and reverse primers selected from the nucleotide sequence which flanks the 132 bp repeat nucleotide sequence of MDV; amplifying the sequence between the primers; detecting the number of repeats; and identifying the type of MDV in the sample.

The teachings of Handberg are described above. Handberg does not teach the 132 bp repeat sequences of MDV.

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Becker et al. (hereinafter Becker) teaches a method of PCR detection of Marek's disease virus type 1 (MDV-1) that amplified MDV-1 (CVI 988, Rispens) DNA sequences containing the 132 bp repeats (Abstract).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to amplify the 132 bp repeat region in a PCR to detect MDV-1. The person of ordinary skill in the art would have been motivated to make that modification because Becker teaches MDV-1 (CVI 988, Rispens) contains multiple copies of 132 bp repeats (Abstract), and reasonably would have expected success because of the teachings of Becker.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Burgess et al. (Journal of Virological Methods, Sept. 1999, Vol. 82, No. 1, pages 27-37) teaches a quantitative PCR for detecting Marek's disease virus (MDV) using two fluorescent dyes to label one PCR primer of each pair to distinguish the products by colour (Abstract).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

September 25, 2007



BRUCE R. CAMPBELL, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



## Notice to Comply

Application No.  
10/530,073

Applicant(s)  
Nair et al.

Examiner  
Sharon Hurt

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### NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: Claims 9 and 10 do not contain a sequence identifier, e.g., SEQ ID NO:1 as required by 37 C.F.R. 1.821(d).

#### Applicant Must Provide:

An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

- ☐ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**
- ☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-0731 or (571) 272-0951  
For CRF Submission Help, call (571) 272-2510  
PatentIn Software Program Support  
Technical Assistance. 1-866-217-9197 or 703-305-3028 or 571-272-6845  
PatentIn Software is Available At [www.USPTO.gov](http://www.USPTO.gov)

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